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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/335,022	06/17/1999	MONIKA JOHANNSEN	20164/109730	5988

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EXAMINER

QAZI, SABIHA NAIM

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 06/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/335,022	Applicant(s) JOHANNSEN, MONIKA	
	Examiner Sabiha Qazi	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Non-Final Office Action

Finality of rejection is withdrawn. Acknowledgment is made of the Appeal Brief filed on Friday, February 20, 2004.

Claims 1-6 are pending in this application. No claim is allowed at the present time.

Presently claimed invention is drawn to a process for the isolation of vitamin D3 or previtamin D3 from a mixture containing vitamin D3 or previtamin D3, which process comprises separating the vitamin D3 or previtamin D3 by a normal phase column chromatographic technique with back-pressure regulation, wherein mobile phase of the chromatography comprises supercritical carbon dioxide.

Claim Rejections - 35 USC § 103(a)

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over HIGASHIDATE et al, SHEN et al, and UPNMOOR et al.

HIGASHIDATE et al teaches enrichment of eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) I from 12% to 93% and from 13% to 82% respectively. Methyl esters of EPA and DHA in esterified fish oil were extracted by supercritical fluid extraction with carbon dioxide and directly introduced into silica gel column coated with silver nitrate. Supercritical fluid chromatography with carbon dioxide was then performed by changing the pressure of the column outlet. Reducing the pressure fractionated the EPA and DHA methyl esters thus separated.

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SHEN et al teaches the separation of vitamins E, A, K1, K2, D2, and D3 on silica columns using supercritical carbon dioxide as a mobile phase.

UPNMOOR et al teaches the use of unmodified and chemically modified silica particles as stationary phase using supercritical carbon dioxide as a mobile phase.

Instant invention is generally taught by the prior art.

One skilled in the art would have been motivated at the time of invention to prepare a process for the isolation of vitamin D3 or previtamin D3 from a mixture containing vitamin D3 or previtamin D3 because the HIGASHIDATE et al reference teaches enrichment of eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) I from 12% to 93% and from 13% to 82% respectively. The SHEN et al reference teaches the separation of vitamins E, A, K1, K2, D2, and D3 on silica columns using supercritical carbon dioxide as a mobile phase. Furthermore, the UPNMOOR et al reference teaches the unmodified and chemically modified silica particles as stationary phase using supercritical carbon dioxide as a mobile phase. The size of the particles is not considered patentably distinct because one skilled in the art who is familiar with the field of chromatography would know how to choose the size of the particle of silica gel. One would consider the size, solvent, pressure, mobile phase, and nature of the mixture to be isolated or separated.

Examiner notes the specific temperature and pressure range cited in claim 6. In absence of any criticality and/or unexpected results, the ranges of temperature and pressure for the isolation of vitamin D3 would have been obvious.

Normally, change in temperature, concentration, or both, is not a patentable modification; however, such changes may impart patentability to a process if the ranges claimed produce a new

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and unexpected result which is different in kind and not merely in degree from results of prior art; such ranges are termed "critical" ranges, and applicant has burden of proving such criticality; even though applicant's modification results in great improvement and utility over prior art, it may still not be patentable if the modification was within the capabilities of one skilled in the art; more particularly, where the general conditions of the claim are disclosed in the prior art, it is not inventive to discover optimum or workable ranges by routine experimentation. In re Aller et al. 105 USPQ 233.

It is well established that merely selecting proportions and ranges is not patentable absent a showing of criticality. In re Becket, 33 U.S.P.Q. 33 (C.C.P.A. 1937). In re Russell, 439 F.2d 1228, 169 U.S.P.Q. 426 (C.C.P.A. 1971).

It is a general rule that merely discovering and claiming a new benefit of an *old* process cannot render the process again patentable. Nor can patentability be found in differences in ranges recited in the claims. When the difference between the claimed invention and the prior art is some range or other variable within the claims, the applicant must show that the particular range is *critical*, generally by showing that the claimed range achieves unexpected results relative to the prior art range. In re Woodruff, 16 USPQ2d 1934.

In the light of the forgoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the instant claims would have been obvious within the meaning of 35 U.S.C. 103(a).

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Communication

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha Qazi whose telephone number is (571) 272-0622. The examiner can normally be reached on any business day.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



SABIHA QAZI, PH.D
PRIMARY EXAMINER

Sunday, June 27, 2004